

PSY56

EXPANDING CONCEPTS OF OPIOID-TAKING BEHAVIOR IN SICKLE CELL DISEASE: A MULTI-PHASE, MIXED METHODS STUDY

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OBJECTIVES: The rapid growth in opioid therapy for non-cancer pain has occurred without an adequate appreciation of the consequences of this growth. Few studies provide patient-centered evidence that can be used to inform the current proposed standards for efficacious (safe and effective) opioid prescribing in non-cancer pain. Furthermore, different terms may be used interchangeably in the literature to refer to opioid-taking behaviors, resulting in imprecise or vague interpretation of existing evidence. We therefore sought to explore patterns of opioid-taking behavior and their biopsychosocial-spiritual determinants in African-American adults with sickle cell disease (SCD). **METHODS:** We conducted a multi-phase mixed methods study which included quantitative and semi-structured qualitative interviews. A grounded theory approach was used to analyze the data. **RESULTS:** The final sample consisted of 11 men and 10 women, average age 36 years. Qualitative thematic analysis uncovered several patterns of opioid-taking behavior and several related biopsychosocial-spiritual phenomena, some hypothesized and some not. These patterns and phenomena portrayed a new six-domain conceptual framework that addresses the complex individual, relational, environmental, cultural, and system issues surrounding opioid taking-behavior in SCD, and provides a roadmap for future research: 1) Pain and its consequences; 2) Prescribed opioid-taking behaviors and their biopsychosocial consequences; 3) Effects of biopsychosocial determinants on opioid-taking behaviors; 4) Aberrant behavior; 5) Physician prescribing behaviors and attitudes; and 6) Hypothetical targets for interventions to improve prescribing and opioid taking-behaviors. Further, the data portrayed explanatory factors that could be classified into various levels or domains based on models proposed in prior research. Factors included within-patient (biological, spiritual, psychological), and social and environmental (social support, provider relationships, institutional norms, culture, legal and governmental policy) domains. **CONCLUSIONS:** The explored domains offer rich guidance toward understanding multi-level explanatory effect of pain, its pharmacotherapy, and medication taking behaviors on SCD individual's health that simultaneously bridges all health care domains.

PSY57

BIOPSYCHOSOCIAL-SPIRITUAL DETERMINANTS OF OPIOID-TAKING BEHAVIOR IN SICKLE CELL DISEASE: A MULTI-PHASE, MIXED METHODS STUDY

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OBJECTIVES: Many questions surround opioid use for non-cancer pain, but little has been published about behavioral patterns of taking opioids in these conditions. The objective of this abstract is to report partial results: patterns of opioid use, and effects of biopsychosocial-spiritual determinants on opioid-taking behaviors. **METHODS:** As part of a multiphase, mixed-method study, we conducted wide-ranging quantitative and semi-structured, qualitative interviews of African-American adults with sickle cell disease (SCD). The final sample consisted of 11 men and 10 women, average age 36 years, from various socioeconomic and educational levels. We used a grounded theory approach to analyze the data. **RESULTS:** Qualitative thematic analysis revealed three phenomena 1) SCD patients exhibited various opioid-taking behavior patterns including adherence, overuse, underuse, and erratic use; 2) A wide variety of biopsychosocial-spiritual factors hindered or motivated opioid use: pain intensity; side effects; fear of addiction; perceived stigma or judgment by others; senses of responsibility, productivity, hopelessness, or obligation; stress; social role pressure; social desirability; bullying; and anticipatory fear of adverse outcomes; and 3) Behaviors varied based on the time of day, week, month, or year, and based on context at times of doses. **CONCLUSIONS:** In summary, we found that contextual factors may drastically affect opioid-taking behaviors. Together, These uncovered phenomena raise new hypotheses that may challenge current theories and models of medication-taking behaviors and methods of assessing adherence. These hypotheses call for a new round of research on opioid-taking behavior, and need to be rigorously tested in future research.

PSY58

A CONJOINT ANALYSIS TO EVALUATE ATTRIBUTE CHOICES AND FEATURE TRADE-OFFS IN OTC ANALGESIC PRODUCT PURCHASE

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OBJECTIVES: To utilize Conjoint Analysis to evaluate the relative importance of extrinsic and intrinsic product attributes in OTC analgesic purchase and examine feature trade-offs in product choice. **METHODS:** A cross-sectional questionnaire survey with profile cards and convenience sample. Consumers shopping at three New York City pharmacies and two convenience stores were recruited and asked to rank order profile cards based on their preference for different combinations of product features. Conjoint analysis employing fractional factorial design with an orthogonal array was used to generate 11 profile cards each for a pair of product attributes (extrinsic and intrinsic). Attributes were analyzed separately and combined, along with multiple levels within each attribute. All feature configurations: price, brand image & promotion (extrinsic); and effectiveness, side effects & dose regimen (intrinsic); were assigned average importance scores and Part-Worth utility scores for all levels within. Importance of each profile relative to other profiles within and across the two attributes was determined. **RESULTS:** The pilot phase of the study (n=32) showed significant Kendall's Tau correlation among profile cards (0.873),

confirming instrument validity. In the main study sample (n=103), with respect to extrinsic attributes, Part-Worth Utility scores indicated price as being the most preferred attribute (1.456) compared to brand image (-1.469) and promotion (0.013). With respect to intrinsic attributes, dose regimen was preferred (1.097) over effectiveness (-0.257), followed by side effects (-0.838). The percentage preference analysis indicated a greater influence of extrinsic features on consumer product choice compared to intrinsic features (57.36% vs. 42.64%). **CONCLUSIONS:** Overall, in decisions regarding choice of a right analgesic product, extrinsic attributes matter more to the consumer than intrinsic features. Brand image and promotional aspects are traded off in favor of price, and dosing convenience is strongly preferred over side effects profile and product effectiveness.

PSY59

WEB-BASED STUDY OF PATIENTS AND CAREGIVERS IN THE UNITED STATES AND CANADA: PERSPECTIVES ON IMPROVEMENTS IN STABILITY OF FACTOR VIII PRODUCTS FOR HEMOPHILIA A

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OBJECTIVES: Hemophilia A is a rare, inherited bleeding disorder in which the affected individual lacks or has limited production of coagulation factor VIII (FVIII), resulting in the inability of the blood to clot normally. Treatment typically involves life-long replacement of FVIII through intravenous infusions to stop or prevent spontaneous or traumatic bleeds. However, FVIII storage and stability remain a constant challenge. Obtaining patients' and caregivers' perspectives is critical to disease management, particularly with rare conditions. A web-based survey was developed to assess hemophilia A patients' and caregivers' preferences around FVIII storage and stability attributes. **METHODS:** Individuals with hemophilia A and caregivers of minor children with hemophilia A from local and national hemophilia support groups in the United States and Canada were invited to complete a web-based survey assessing patients' FVIII ordering, usage, and storage routines. **RESULTS:** Of the 145 individuals who responded to the survey invitation, 101 individuals (67% caregivers [82% female]) completed the survey (70%). Nearly half (48%) of respondents ordered FVIII monthly, and 8% reported often having FVIII vials expire before their use. Challenges to storing FVIII included refrigeration when traveling (28%) and carrying an insulated tote bag (27%). More than half (54%) preferred a new FVIII product with longer storage at room temperature. The majority (80%) indicated preference for a FVIII product that could be stored at a higher room temperature for longer durations, primarily for ease in traveling, keeping more factor at home, and having easy access when needed. **CONCLUSIONS:** This web-based study provides a unique perspective from patients and caregivers on treatment attributes that are important to this population. There is a need for an improved FVIII product that offers more convenience and faster access to patients in daily life and while traveling. Additionally, flexibility in storage potentially could reduce the frequency of FVIII wastage.

PSY60

CHANGES IN PAIN INTENSITY AND HEALTHRELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WITH PERIPHERAL NEUROPATHIC PAIN AFTER TREATMENT WITH 8% CAPSAICIN PATCH - RESULTS FROM A NORDIC PROSPECTIVE OBSERVATIONAL STUDY

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OBJECTIVES: To examine the effect of 8% capsaicin patch on change in "usual pain" using a modified PNRS (Pain Numeric Rating Scale). A secondary objective was to examine utility scores assessed by the EQ-5D-3L. **METHODS:** Adult patients diagnosed with peripheral neuropathic pain (excluding diabetic polyneuropathy) were included. Each patient was eligible to receive up to two treatments. Parameters: PNRS, patient's pain intensity over the past 24 hours: usual, highest, lowest and right now EQ-5D-3L Size of treated area **RESULTS:** A total of 412 patients were included, 382 patients completed first treatment period, 266 with partial peripheral nerve injury; 51 with post herpetic neuralgia (PHN); 19 with polyneuropathy and 46 with other painful neuropathies. Fifty-nine percent were women, mean age was 53 years (range 18-88). A total of 184 patients were given a re-treatment and 181 patients completed the re-treatment period. PNRS: Usual pain intensity over the past 24 hours (maximum pain reduction at any time point) decreased from 6.3 to 4.4 (p < 0.001) and at re-treatment from 6.3 to 5.0 (p < 0.001). Mean EQ-5D health score was 0.33 (SD 0.32) at baseline (range -0.38-1.00). During the post-treatment period the mean change was 0.25 (SD 0.29), (p < 0.001). At baseline, 58% of all patients reported "Extreme Problem" in the pain/discomfort dimension and corresponding figures for the post-treatment period was 38%. Mean EQ-5D health score was 0.54 (SD 0.32) at start of re-treatment (range -0.26-1.00). During the post-re-treatment period the mean change was 0.17 (SD 0.28 (p < 0.001). The area treated had at baseline a median size of 180 cm² and at re-treatment 160 cm². **CONCLUSIONS:** In this population of patients with peripheral neuropathic pain and a markedly reduced QoL, treatment of capsaicin 8% significantly reduced patients' experience of "usual pain" and improved short-term HRQoL evaluated by EQ-5D-3L.

PSY61

WHO TOLD YOU THAT: DO GUIDELINES FOR INCLUDING PATIENT-CENTERED OUTCOME MEASURES IN SYSTEMIC LUPUS ERYTHEMATOSUS CLINICAL TRIALS INCLUDE PATIENT INPUT?

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OBJECTIVES: The importance of patient-centered outcomes (PCO) in drug development is increasingly recognized by health authorities, clinical advisory and patient advocacy bodies. Accordingly, many of these organizations seek to include PCO in their guidelines and recommendations. However, complex disorders present measurement challenges that are difficult to resolve within the scope of a clinical trial (CT). An example is Systemic Lupus Erythematosus (SLE), characterized by myriad clinical indicator, symptom, severity and frequency combinations. SLE patient burden studies demonstrate that, while symptoms differ, the impact is universal. This study evaluates the relationship between recently updated SLE guidances and concepts reported directly by SLE patients.

METHODS: A qualitative study comprised of six SLE patient focus groups (N=43) was conducted to elicit direct patient input on key symptoms and concepts. FDA and EMA guidelines for SLE clinical trials, European League Against Rheumatism (EULAR) CT endpoint recommendations, and the Systemic Lupus International Collaborating Clinics (SLICC) classification system were evaluated for PCO-specific content. Patient-reported outcomes (PRO) concepts from the study were then compared to the PCO content from the guidelines and recommendations.

RESULTS: All study subjects (mean age 44.3 years; 91.7% women; 63% diagnosed ≥ 5 years; 91% experienced flare ≤ 3 months; 74% mild/moderate disease) identified fatigue among "most important symptoms" with 98% citing pain and 44% fog/confusion. Regardless of "importance" all subjects deemed other symptoms highly disruptive. EMA and FDA both specify fatigue as a clinical trial endpoint. FDA included "fatigue" based on clinician input, but recommended development of a PRO-based fatigue exploratory endpoint. EULAR, citing challenges of symptom endpoints, suggested general Health-Related Quality of Life. The SLICC didn't mention PCOs. **CONCLUSIONS:** Patients identified multiple SLE symptoms and impacts, yet guidances didn't address these issues. Joint efforts between patients, sponsors, regulators and advisory organizations are necessary to implement relevant PCOs, especially in complex disorders.

PSY62

COMPARISON OF CLINICAL AND COST CHARACTERISTICS AMONG PATIENTS WITH INFLAMMATORY BOWEL DISEASE ACROSS DIFFERENT SITES OF CARE

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OBJECTIVES: To compare clinical and cost characteristics among patients with inflammatory bowel disease (IBD) receiving biologic medication in an in-office setting (IOI), hospital outpatient department (HOPD), or ambulatory clinic.

METHODS: A syndicated study of IBD patients was conducted. Patients aged ≥ 18 years were recruited via the National Health and Wellness Survey and Lightspeed Research Panel to complete a survey during August–November 2010. Patients were asked about health care utilization, concomitant medications, IBD symptoms, quality of life (QoL) and out-of-pocket (OOP) costs. To measure utilization, the number of provider, emergency room (ER), and hospital visits in the past 6 months was collected. The Medical Outcomes Study (MOS) IBD questionnaire was used to assess QoL. Bivariate differences were assessed using Fisher's exact tests for categorical variables and ANOVAs for continuous variables. **RESULTS:** Of 175 IBD patients, 54% (n=94) received biologic medication in an IOI setting, 35% (n=61) in an HOPD setting, and 11% (n=20) in an ambulatory clinic. The number of ER and hospital visits were similar across groups, however IOI patients had greater provider visits (p<0.05). Though concomitant medication utilization was generally similar, significantly more IOI patients received steroids compared to HOPD patients (p<0.05). Most IBD symptoms did not differ across groups. However, HOPD patients were more likely to have fistulas than IOI patients (30% vs. 16%; p<0.05), and IOI patients were less likely to experience bowel movements than HOPD or clinic patients (55% vs. 84% and 80%, respectively). HOPD patients had lower OOP costs for biologic medications and higher QoL scores compared to IOI patients (p<0.05). **CONCLUSIONS:** Among IBD patients receiving biologic medication in an IOI, HOPD, or ambulatory clinic setting, HOPD patients had higher QoL and lower OOP costs, however, few other differences were identified. Further research is needed to elucidate these findings.

PSY64

CORRELATES OF IMPROVEMENT IN PHYSICAL QUALITY OF LIFE AND QUALITY OF SLEEP AMONG CHRONIC LOW BACK PAIN PATIENTS WITH TREATMENT WITH BUPRENORPHINE TRANSDERMAL SYSTEM (BTDS)

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OBJECTIVES: Deficits in physical health-related quality of life (HRQL) and sleep quality in chronic low back pain (CLBP) patients may be alleviated with Buprenorphine Transdermal System (BTDS) treatment. This post-hoc analysis of clinical trial data aimed to explore whether BTDS treatment has a direct impact on HRQL and sleep quality, an indirect impact on the outcomes as mediated through its impact of pain, or both; and to identify significant correlates of HRQL and sleep quality. **METHODS:** In this multicenter, enriched, double-blind, randomized trial, opioid-naïve patients with moderate-to-severe CLBP received twelve weeks' treatment with BTDS (10 or 20 mcg/hour) or placebo. A series of multivariate linear regression models (stepwise) predicting physical HRQL, sleep disturbance, and sleep quality at week 12 were fitted. Physical HRQL was measured using the SF-36v2 Physical Component Summary (PCS), while sleep outcomes were measured using the Disturbance subscale and Sleep Problems Index (SPI) of the Medical Outcomes Study Sleep Scale (MOS-SS). For each outcome, models 1 and 2 included baseline demographic and clinical variables, model 3 added treatment arm, and model 4 added pain assessment at week 8. **RESULTS:** Results from model 3 supported BTDS treatment as a significant predictor of better physical HRQL and sleep outcomes. Model 4 results for each

outcome indicated that pain was a partial mediator of treatment on physical HRQL and sleep quality, meaning that treatment had both direct and indirect effects on these outcomes. Mid-trial pain and the baseline value of the outcome being tested (i.e., PCS score, Disturbance score, or SPI score) were the strongest predictors for each outcome. **CONCLUSIONS:** For CLBP patients, improvements in physical HRQL, sleep disturbance, and sleep quality were impacted by BTDS treatment both directly as well as indirectly via mediation through the treatment-driven reductions in pain. Mid-trial pain strongly predicted to HRQL and sleep outcomes.

PSY65

RESPONSIVENESS AMONG PATIENT-REPORTED MEASURES OF QUALITY OF LIFE, QUALITY OF SLEEP, AND FUNCTIONAL DISABILITY TO PAIN AND IMPACT OF BUPRENORPHINE TRANSDERMAL SYSTEM (BTDS) TREATMENT IN CHRONIC LOW BACK PAIN PATIENTS

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OBJECTIVES: Patients with moderate-to-severe chronic low back pain (CLBP) who are treated with Buprenorphine Transdermal System (BTDS) experience improvements in three patient-reported outcomes: quality of life (QoL), sleep quality, and functioning. This analysis compared the relative responsiveness of measures of each outcome to treatment and treatment-driven changes in pain.

METHODS: This post-hoc analysis used data from an enriched, 12-week double-blind, randomized placebo-controlled trial evaluating BTDS (10 or 20 mcg/hour) for treatment of pain in opioid-naïve patients with moderate-to-severe CLBP. The trial repeatedly assessed QoL (SF-36v2), sleep quality and problems (Medical Outcomes Study Sleep Scale [MOS-SS]), and functional disability (Oswestry Disability Index [ODI]) in addition to measures of pain. Responsiveness of each instrument to treatment and changes in pain were examined using analysis of covariance, t-tests, and effect sizes for comparison of effects of time, treatment, and magnitude of pain reduction. The interrelation among PROs was also examined. **RESULTS:** The SF-36v2 and ODI showed better responsiveness to treatment and changes in pain than did the MOS-SS. Among subscales of the MOS-SS, only Disturbance showed substantial correlations with other PRO and pain measures and substantial differences across time, treatment, and pain reduction status groups. Several of the QoL domains measured by the SF-36v2, particularly Bodily Pain, Physical Functioning, Role Physical, Social Functioning, and Vitality, showed considerable responsiveness to treatment and pain. For the ODI, the Pain Intensity subscale showed the greatest responsiveness, with the majority of the remaining subscales showing more moderate, but still meaningful, levels of responsiveness. PRO measures were, in general, moderately inter-correlated, particularly between SF-36v2 and ODI subscales. **CONCLUSIONS:** Pain subscales on the SF-36v2 and ODI showed the greatest responsiveness to treatment. Substantial responsiveness was also observed for the majority of QoL and functioning domains, as well as sleep disturbance. Subscales of PRO instruments were generally moderately inter-correlated.

PSY66

CONTENT VALIDITY OF A NEW OBESITY-SPECIFIC HEALTH RELATED QUALITY OF LIFE (HRQOL) INSTRUMENT – FABQOL

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OBJECTIVES: Obesity has become a major public health problem worldwide. In Singapore, the prevalence of obesity among adults aged 18-69 years increased from 6.9% in 2004 to 10.8% in 2010. To the best of our knowledge, no single obesity-specific HRQOL instrument comprehensively covered areas of life that are important to obese individuals. Therefore we sought to assess the content validity of FABQOL, a newly developed instrument, to address the gap.

METHODS: FABQOL (76 items) was developed based on literature review and mapped to obesity-specific International Classification of Functions Disability and Health (ICF) categories. Content validity (i.e. item comprehension and content coverage) was assessed through individual cognitive debriefing interviews with 30 English-speaking, ethnic Chinese, Malay and Indian overweight/obese patients from a weight management clinic at a public hospital in Singapore. For each item, we asked participants if the item was important to them (yes/no). Items that were perceived as not important by at least 50% of the participants and items that were not understood by at least 20% of the participants were removed. Participants were also asked to suggest additional items that were important. **RESULTS:** Participants aged from 23-58 years (median age = 45), one-third were men and 90% were obese (BMI ≥ 27.5 kg/m²). Two items "being able to eat as much as I want to" and "being able to reach for objects placed above me" were perceived as not important by 26 (87%) and 15 (50%) of participants respectively. Four items ("lethargic", "distressed", "anxious" and "stigmatized") were removed because they were poorly understood. Three participants suggested three new items pertaining to relationship with close friends, company image and personal leisure activities. **CONCLUSIONS:** The revised FABQOL comprises 73 items that were generally easy to understand and important to overweight/obese patients in Singapore. Psychometric properties of FABQOL will be evaluated in a larger study.

PSY67

LONGITUDINAL CHANGES IN HEALTH-RELATED QUALITY OF LIFE FOR CHRONIC DISEASES: AN EXAMPLE FROM THE HEMOPHILIA UTILIZATION GROUP STUDY PART VA (HUGS VA)

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